UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FWK Holdings, L.L.C., on behalf of itself and all others similarly situated,

Plaintiff,

vs.

MYLAN, INC., TARO PHARMACEUTICAL INDUSTRIES LTD., TARO PHARMACEUTICALS USA, INC., and SANDOZ, INC.,

Defendants.

No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. Plaintiffs FWK Holdings, L.L.C., on behalf of itself and all others similarly situated (collectively "Plaintiffs"), bring this Class Action Complaint on behalf of a Class (defined below) of direct purchasers who purchased generic clomipramine hydrochloride in its 25 mg, 50 mg and 75 mg oral capsule forms ("clomipramine") directly from defendants Taro Pharmaceutical Industries Ltd. ("Taro Ltd."), Taro Pharmaceuticals USA, Inc. ("Taro Inc.") (collectively, "Taro"), Mylan, Inc. ("Mylan") and Sandoz, Inc. ("Sandoz").

2. Defendants and co-conspirators engaged in an overarching anticompetitive scheme in the market for generic clomipramine to artificially inflate prices through unlawful agreements between and among would-be competitors. Plaintiffs seek damages incurred due to Defendants' and co-conspirators' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

3. The direct, foreseeable, and intended consequence of Defendants' anticompetitive scheme was to cause Plaintiffs and Class Members to pay more for generic clomipramine than they otherwise would have paid in the absence of Defendants' unlawful conduct. As set forth below, Defendants' scheme violates Section 1 of the Sherman Act, 15 U.S.C. § 1 ("Sherman Act").

4. Plaintiffs make the allegations herein based on personal knowledge of these matters relating to itself and upon information and belief as to all other matters.

II. NATURE OF THE CASE

5. For years, Defendants colluded to restrain and/or eliminate competition by engaging in a conspiracy to foreclose competition in the United States market for generic clomipramine, a medically-important and widely-prescribed tricyclic antidepressant, in violation of Section 1 of the Sherman Act. Through this anticompetitive conduct, Defendants have imposed unlawful overcharges on generic clomipramine purchasers.

6. Plaintiffs seek redress for the overcharge damages resulting from Defendants' unlawful conspiracy and other anticompetitive conduct in violation of Section 1 of the Sherman Act. Were it not for Defendants' illegal conduct, Plaintiffs and Class Members would not have paid supracompetitive prices for generic clomipramine.

7. Plaintiffs' allegations are based in part on information made public during government investigations of Defendants for alleged unlawful conduct in the generic drug industry. In 2014, the U.S. Department of Justice, Antitrust Division ("DOJ") began investigating alleged criminal conduct in the generic drug industry, leading to the issuance of a grand jury subpoena from the DOJ to Defendants Mylan Pharmaceuticals Inc. and Taro Pharmaceuticals USA, Inc. on September 8, 2016. Public filings disclose that the DOJ is investigating defendants' generic drug pricing, and generic clomipramine is not the only drug at issue.

8. The DOJ's 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing.[1] The NCPA's news release reports price hikes on essential generic drugs exceeding 1,000% in some instances, according to its survey of over a thousand community pharmacists, resulting in patients being forced to leave their prescriptions at the pharmacy counter due to increased copays, and forcing more seniors into Medicare's coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs. And because of the

s[1] News release available at http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

months-long delays in pharmacy benefits managers and other third party payers updating their reimbursement rates, pharmacies are losing money from the price hikes as well – up to $100 or more per prescription filled – losses small community pharmacies are unable to absorb. The clear majority of the surveyed community pharmacies said these losses were unsustainable and posed a significant threat to their ability to continue serving patients.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 4 of the Clayton Act, 15 U.S.C. §§ 15. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

10. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b) and (c), because during the Class Period the Defendants transacted business throughout the United States, including in this District.

11. During the Class Period, Defendants sold and distributed generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic clomipramine in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

12. This Court has personal jurisdiction over each Defendant because, inter alia, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of generic clomipramine throughout the United States, including in this District; (c) had and maintained substantial contacts within the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for generic clomipramine that was directed at and had the intended effect of causing injury

to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. PARTIES

A. Plaintiff

13. Plaintiff FWK Holdings, L.L.C. is an Illinois limited liability company located in Glen Ellyn, Illinois. Plaintiff is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of clomipramine during the Class Period directly from one or more of the Defendants at artificially and unlawfully inflated prices.

B. Defendants

14. Defendant Mylan is a Pennsylvania corporation that has its principal place of business in Canonsburg, Pennsylvania. Mylan develops, manufactures, and markets prescription drugs, including clomipramine, throughout the United States. Mylan owns and operates production and office facilities in Caguas, Puerto Rico and Morgantown, West Virginia. During the Class Period, Mylan sold generic clomipramine to purchasers in this District and throughout the United States.

15. Defendant Sandoz is a Colorado corporation with its principal place of business in Princeton, New Jersey. Sandoz develops, manufactures, and markets prescription drugs, including clomipramine, throughout the United States.

16. Defendant Taro Pharmaceutical Industries Ltd. ("Taro Ltd.") is an Israeli company with its principal place of business in Haifa Bay, Israel. Taro Ltd. develops, manufactures, and markets prescription drugs, including clomipramine, throughout the United States. Taro Ltd. has operated in the United States principally through its subsidiary, Defendant

Taro Pharmaceuticals USA, Inc. ("Taro Inc."). During the Class Period, Taro Ltd. sold generic clomipramine to purchasers in this District and throughout the United States.

17. Defendant Taro Inc. is a New York corporation with its principal place of business in Hawthorne, New York. Taro Inc. is the wholly-owned subsidiary of Taro Ltd. and is responsible for the marketing and sale of generic clomipramine throughout the United States. During the Class Period, Taro Inc. sold generic clomipramine to purchasers in this District and throughout the United States.

18. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants' officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of Defendants' business and affairs.

V. UNIDENTIFIED CO-CONSPIRATORS

19. Various other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

20. The true names and capacities, whether individual, corporate, associate, or representative, is presently unknown to Plaintiffs. Plaintiffs may amend this Complaint to allege the true names and capacities of additional co-conspirators as they are discovered.

21. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful monopolization as described herein.

22. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized

officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

VI. FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

23. Generic drugs provide a lower-cost but bioequivalent alternative to brand name drugs. Before any generic drug can be marketed, FDA requires rigorous testing to ensure it has the same strength, quality, safety, and performance as the brand name. By law, generics must have the exact same amount of active ingredient and must be "therapeutically equivalent" to the brand, meaning they must meet exacting bioequivalence testing specifications so patients can expect "equal effect and no difference when [generics are] substituted for the brand name product." [2]

24. To obtain marketing approval for a generic drug, an Abbreviated New Drug Application ("ANDA") must be filed with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs; "abbreviated" because so long as the ANDA includes data showing bioequivalence to the brand, the ANDA sponsor can reference efficacy data supporting approval of the brand (described in the regulations as the "Reference Listed Drug" or "RLD" for short) instead of repeating all the same clinical trials itself. Upon the FDA's determination that bioequivalence to the brand has been established, the ANDA will be approved and may be marketed in the U.S. as substitutable with the RLD.

25. Although equivalent from a safety and efficacy standpoint, generic versions of brand name drugs are priced significantly below their brand name counterparts, and because of this rapidly gain market share from the brand beginning immediately following launch. Indeed,

[2] http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

in every state pharmacists are permitted (and in many states required) to substitute a generic product for a brand name product a note from a doctor that the brand name product must be dispensed as written.

26. It is well established in economic literature that competition by generic products results in lower prices for drug purchasers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price free from competitive market forces. But once the first lower-priced generic enters, a brand name drug rapidly loses sales due to automatic pharmacy counter substitution, and generics capture as much as 80% of the market or more within months of launch. And as more generics become available, generic prices only decline further due to competition among generics, and the brand drug's share of the overall market erodes even faster. These cost reductions to drug purchasers were the very legislative purpose behind the abbreviated regulatory pathway for generic approval.[3]

27. Generic competition, under lawful and competitive circumstances, reduces drug costs by driving down the prices of both generic versions of the brand name drug and the brand name drug itself, and every year new generic drugs result in hundreds of billions of dollars in savings to consumers, insurers, and other drug purchasers.

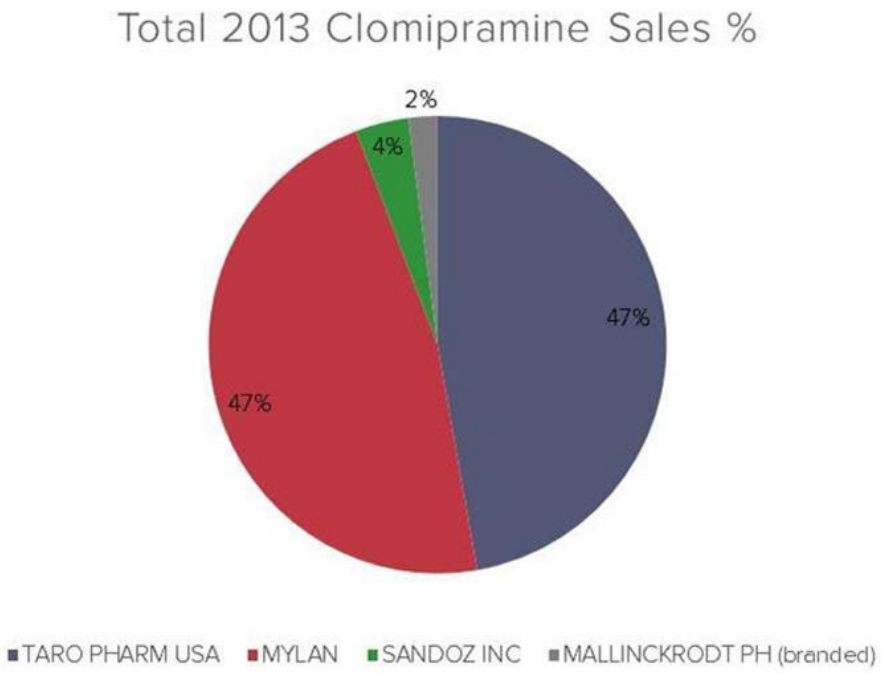
B. Generic Clomipramine Market and Pricing Information

28. Generic clomipramine is a prescription oral tricyclic antidepressant used to treat obsessive compulsive disorder, panic disorder, major depressive disorder, and chronic pain. The market for generic clomipramine is mature, as generic versions have been on the market since 1996. Hundreds of thousands of prescriptions are filled per year for this drug, which is on the

[3] H.R. Rep. No. 98-857, pt. 1, at 1 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2647.

World Health Organization's List of Essential Medicines as one of the most important medications needed in a basic health system. In 2015 alone, total sales revenue for clomipramine spiked to $519 million, which is more than half the total sales revenue for the same products from 2011-2014 combined. This type of revenue growth in a mature is evidence of Defendants collusion.

29. During the entirety of the class period, the defendants dominated the clomipramine market, with their sales making up about 98% of all U.S. clomipramine sales:



30. In terms of volume, in 2013, Mylan's Clomipramine sales exceeded $96.14 million, Taro's clomipramine sales exceeded $96.67 million, and Sandoz's sales exceeded $7.66 million.

31. A mature generic market, such as the market for clomipramine, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main

differentiating feature and the basis for competition among manufacturers.[4] Over time, generics' pricing nears the generic manufacturers' marginal costs.

32. The pricing of prescription pharmaceutical products in the U.S. is governed by institutional features typically not present in the marketplace for other consumer products.

33. Ordinarily, the price for a consumer product is set by the retailer based on the amount the typical consumer is willing to pay. Because of the unique features of the prescription drug marketplace, however, pricing of prescription drugs for most consumers is not determined between the retailer and the consumer. Rather, because most consumers' prescription drug purchases are reimbursed by public or private health plans, the pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payors, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payors' insured customers.

34. At one time, payors relied on cost-based pricing metrics to reimburse pharmacies that dispensed drugs to their insured customers, paying the dispensing pharmacies an amount based on the manufacturer's list price for the drug, plus a small mark-up and/or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

[4] *See, e.g.*, FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at 17 (Aug. 2011)("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."); U.S. Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Proceed and Returns in the Pharmaceutical Industry* (July 1998), *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

35. To reduce the cost of prescription drugs to the public, prescription drug payors developed Maximum Allowable Cost prices ("MACs") to determine the amount that pharmacies would be reimbursed for dispensing generic pharmaceuticals. The MAC price refers to the maximum amount that a payor will reimburse a pharmacy for a given strength and dosage of a generic drug or brand name drug that has a generic version available. A MAC price thus represents the upper limit that a prescription drug payor will pay a pharmacy for a generic drug.

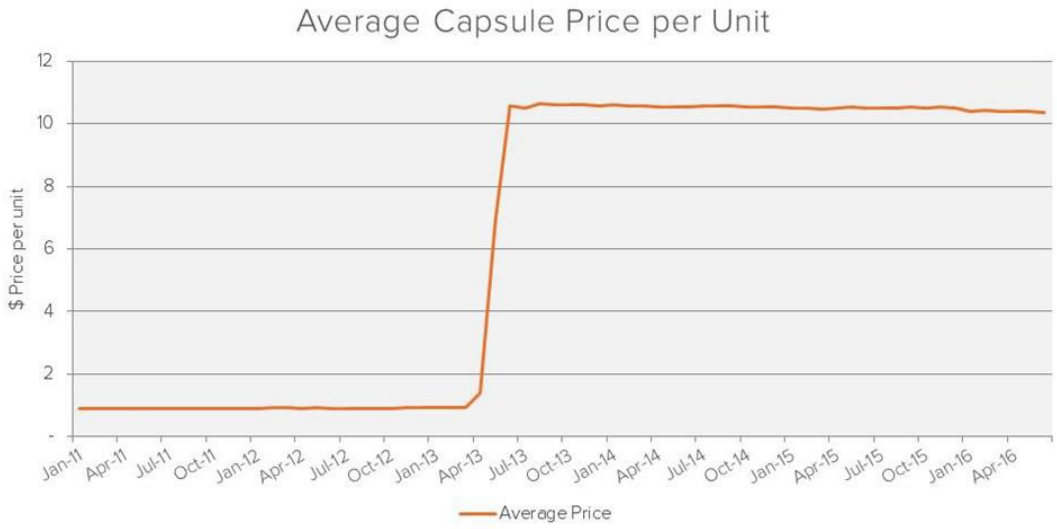
36. Payors set the MAC pricing of a drug based on a variety of factors, including, most significantly, the lowest acquisition cost for each generic drug paid by retail pharmacies purchasing from a wholesaler for each of a drug's generic versions.

37. MAC pricing is designed to incentivize pharmacies to purchase the least costly version of a generic drug available on the market, without regard to the manufacturer's list price. Because the reimbursement amount to a pharmacy is limited by the MAC price for a generic drug and each of its equivalents regardless of the pharmacy's acquisition cost, a pharmacy's profit will be reduced, or lost altogether, if it purchases other than the lowest cost generic product. Alternatively, if a retail pharmacy purchases the lowest priced generic version of the drug, it will maximize its profit.

38. MAC pricing also incentivizes an individual generic manufacturer to refrain from unilaterally increasing its prices. Because MAC pricing bases reimbursement on the generic drug's lowest acquisition cost, a generic manufacturer that increases its price for a drug while competing manufacturers do not will swiftly lose sales to a competing generic manufacturer whose price remains constant.

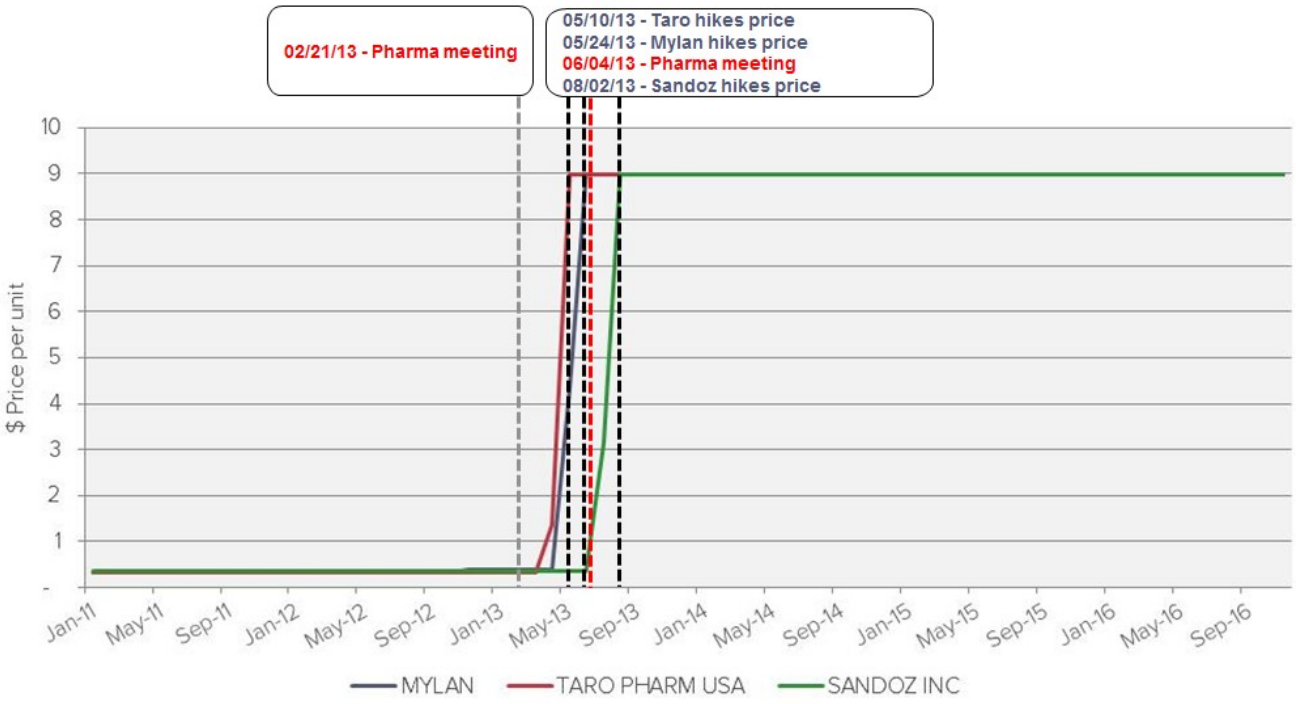
39. Consequently, in the absence of coordinated pricing activity among generic manufacturers, and individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales.

40. Before May 2013, generic clomipramine pricing had for years remained stable, as is typical in a mature market, at $0.94 per capsule. However, prices inexplicably increased sharply in the three months following February 2013, which is when generic pharmaceutical manufacturers met for a 3-day conference in Orlando, Florida, skyrocketing more than 1000% to over $10 per capsule.



41. These price hikes were exorbitant and lock-step, as shown by the list price data tabulated and graphically depicted below:

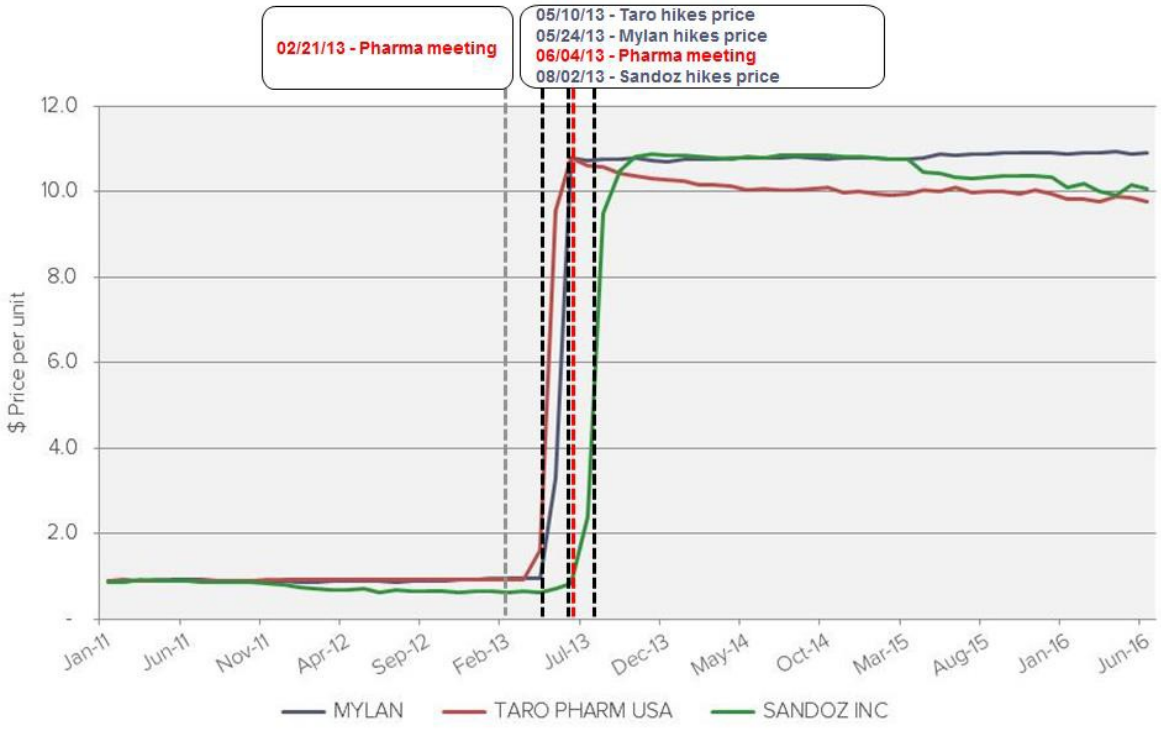
Manufacturer	4/26/2013	5/3/2013	5/24/2013	7/26/2013
Taro	$0.33	$8.99	$8.99	$8.99
Mylan	$0.39	$0.40	$8.99	$8.99
Sandoz	$0.35	$0.36	$0.37	$8.99



42. The list price increase, in turn, had a direct impact on the Average Wholesale Price ("AWP") for clomipramine, which is the average price paid by wholesalers, as tabulated below:

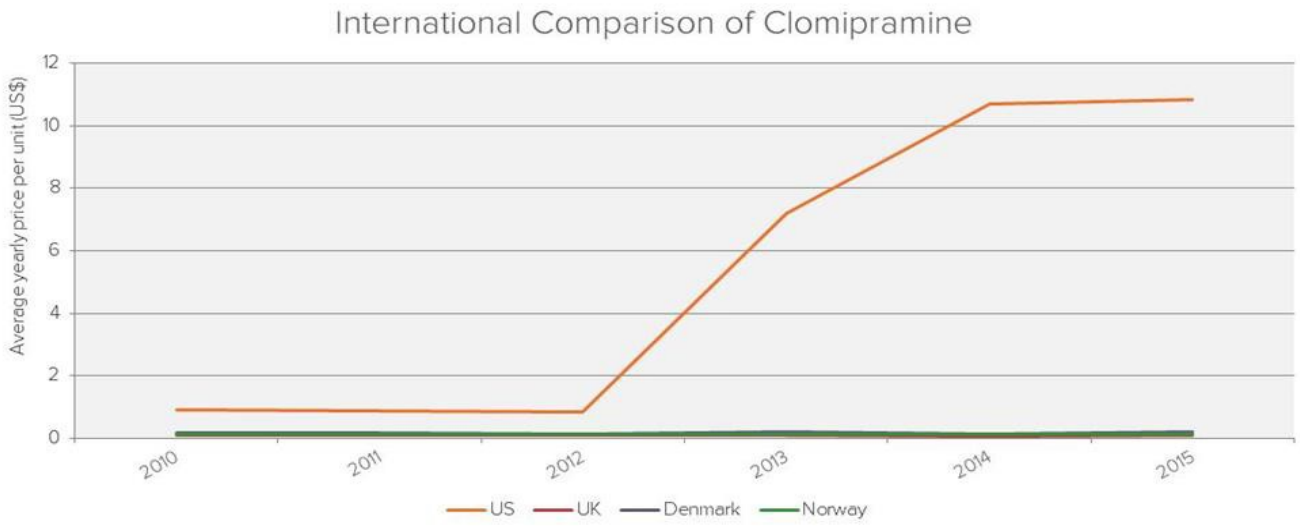
Manufacturer	3/29/2013	8/30/2013	9/30/2013
Taro	$0.94	$10.58	$10.44
Mylan	$0.94	$10.77	$10.76
Sandoz	$0.66	$9.49	$10.48

43. Finally, the retail pharmacy level purchasers likewise took a hit from the shockwave of price hikes down the pharmaceutical distribution chain:

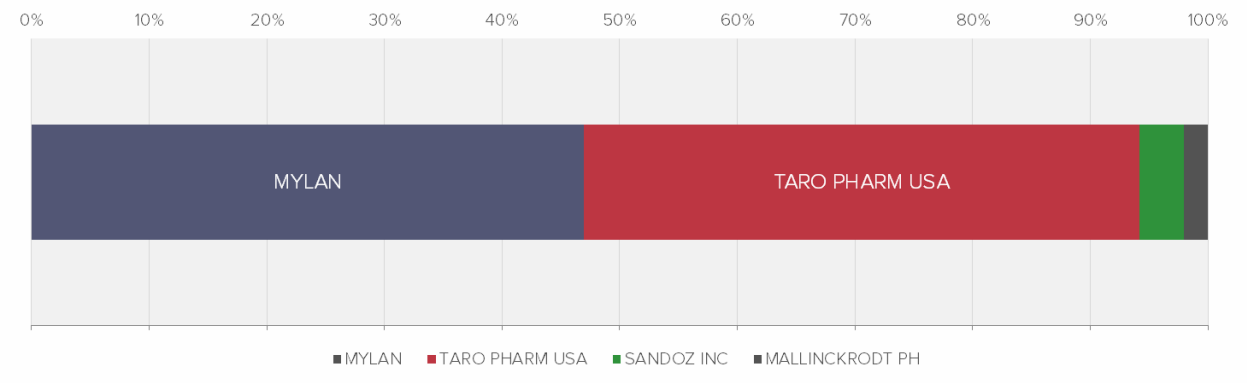


44. There are no potential drug shortages or supply disruptions, or any other lawful market phenomena, to explain the price increases. Federal law requires mandatory drug shortage reporting for drug manufacturers.[5] None of the Defendants reported any drug shortages or supply disruptions to the FDA in explanation for the supracompetitive pricing of clomipramine. And even Defendants themselves cannot muster any meaningful explanation for the coordinated price increases. Tellingly, there were no similar price hikes in other countries, including, for example, in the United Kingdom, Denmark, or Norway, where prices have remained flat.

[5] Title IX of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA")

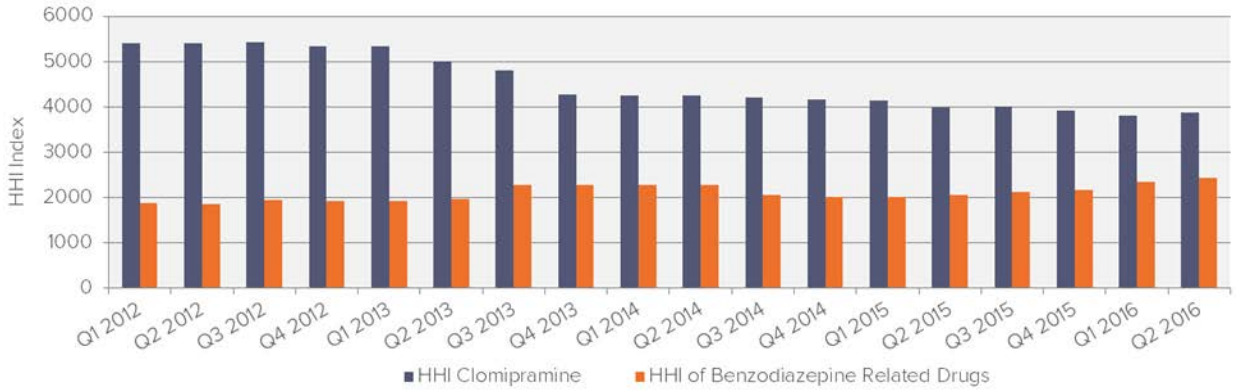


45. Nor does any change in marketplace explain the rising prices—in 2013, defendants accounted for around 98% of the annual clomipramine sales, and for years the prices and respective market shares of competitors had remained relatively constant at these levels:



46. There have been at least three separate manufacturers of generic clomipramine on the market at all relevant times during the class period. Under accepted economic principles of competition, when there are multiple generics on the market, prices should remain at highly competitive, historic levels, and would not increase as they did here absent anticompetitive conduct; that increase is itself suggestive of Defendants' collective market dominance, absent which their pricing excesses would be disciplined by losing market share to non-colluding competitors. Defendants' collective dominance is also apparent when comparing the Herfindahl-

Hirschman Index ("HHI") scores for clomipramine and benzodiazepine (another generic drug). HHI is a standard measure of firm concentration in relation to a given industry and an indicator of the amount of competition in that industry. An HHI score of 0 indicates perfect competition whereas a score of 10,000 indicates a monopoly. The DOJ classifies an industry as "concentrated" if the HHI exceeds 1,800 and "highly concentrated" if it exceeds 2,500.[6] As shown below, since the beginning of 2012, clomipramine's HHI on average shows a highly-concentrated market. In contrast, the benzodiazepine index was only half that of clomipramine during the same timeframe and its price movements demonstrated relative stability:



C. Defendants' Anticompetitive Activities

47. During the Class Period, Defendants conspired, combined, and contracted to fix, raise, maintain, and stabilize prices at which generic clomipramine would be sold, which had the intended and actual effect of causing Plaintiffs and the other members of the proposed Class to pay artificially inflated prices above prices that would exist competitive market had determined prices for generic clomipramine.

[6] *See* https://www.justice.gov/atr/herfindahl-hirschman-index.

1. Annual Reports and Investor Communications

48. Defendants' statements and admissions in their annual reports and other investor communications reveal defendants goal of increasing generic drug prices and maintaining them at supracompetitive levels.

a. Mylan

49. In a Q3 2015 earnings call, Mylan's CEO and Mylan's EVP and CFO repeatedly commented on the "positive pricing environment that we've seen, especially over the last couple of years in North America" and that Mylan had "absolutely had opportunities around generic pricing." Mylan executives made similar comments relating to the "positive pricing environment" in earlier earnings calls, such as the Q4 2014 earnings call.

50. On October 7, 2016, Mylan disclosed in a filing with the U.S. Securities and Exchange Commission ("SEC") that on September 8, 2016, the DOJ "subpoenaed a company subsidiary, a senior executive and other employees about alleged price fixing and also executed multiple search warrants related to its probe." Mylan further disclosed that the DOL is seeking "additional information relating to the marketing, pricing and sale of" several generic drugs, "and any communications with competitors about such products."

b. Sandoz

51. According to a *Bloomberg News* article, Sandoz has confirmed that it received a subpoena from the DOJ in March 2016, and stated that it believed the subpoena was related to "the industry-wide investigation into generic drug pricing in the U.S."[7]

[7] https://www.bloomberg.com/news/articles/2016-11-17/nypd-union-goes-after-drug-prices-amind-doj-pharma-investigation.

c. Taro

52. During a November 10, 2014, earnings call, Taro CEO Kal Sundarum attributed the company's significant growth to price increases:

> In 2010, as per IMS data, Taro was ranked third among the genetic dermatology companies in USA. In terms of sales, now it is ranked number one for the past three years. U.S. remains the dominant market for Taro. Taro's earnings per share also has grown 50% CAGR, compounded annual growth, since 2010. Taro's sales and earnings growth is attributable to upward price adjustments and the prudent life cycle management of our product portfolio while our overall volumes remain relatively constant and we remain cautious about the long-term sustainability of these prices. Our sales and earnings growth is attributable to upward price adjustments and prudent life cycle management of our portfolio, while our overall volumes remain relatively constant. Again market to volume fluctuations can happen for very different reasons as and when a new generation product comes, it will have impact on the older generation product. And once again I am saying generics remain to be sort of, what do you say cost value for money and competitive. I don't think there will be any significant -- we have seen any significant impact of volume shifting because of price adjustments.

53. Sundarum again emphasized Taro's strategy of relying upon high-priced generics in a November 4, 2015, earnings call, stating that "We are a specialty generic company, so by definition, our portfolio will be obviously narrow but sort of focused. We operate in niche markets; smaller volumes, but better priced."

54. On September 9, 2016, Taro disclosed in an SEC filing that "Taro Pharmaceuticals, U.S.A., Inc. . . . as well as two officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters."

2. Defendants' Collusion Opportunities through Trade Organizations.

55. Defendants have ample opportunities to communicate through trade organizations, and have availed themselves of those opportunities to collude.

56. The industry intelligence-gathering reporting firm *Policy and Regulatory Report* ("PaRR") has reportedly obtained information regarding the investigation of generic drug companies by the DOJ, and has indicated that the DOJ is investigating the extent to which trade organizations have been used as forums for collusion between sales personnel among competing generic drug companies.[8]

57. For example, the Generic Pharmaceutical Association ("GPhA") is the "leading trade association for generic drug manufacturers."[9] GPhA was formed in 2000 from the merger of three industry trade associations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

58. GPhA's website touts, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry" and lists its "valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."[10] GPhA's "member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year."

[8] http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07.

[9] http://www.gphaonline.org/about/the-gpha-association.

[10] http://www.gphaonline.org/about/membership.

59. Defendants each attended a GphA meeting in Florida in February 2013 and another such meeting in Bethesda, Maryland, in Jun 2013, which was sponsored by defendant Mylan.

3. Industry Commentary

60. Comments from industry analysts suggest manufacturers' alternative explanations for the price hikes (e.g., supply disruptions) are mere pretextual, intended to shroud the Defendants conspiratorial conduct and ends. For instance, Richard Evans at Sector & Sovereign Research recently wrote: "[a] plausible explanation [for price increases] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation."[11]

61. A *Bloomberg* reporter, Alan Katz, wrote on December 12, 2013 that:

> Bill Drilling, an owner of a pharmacy in Sioux City, Iowa, apologizes as he rings up a customer's three-month supply of the heart medicine digoxin. The total is $113.12— almost 10 times the cost for the same prescription in August.
>
> * * *
>
> "This is starting to create hardship," he says. Many of his customers fall into what is known as the Medicare "doughnut hole," a coverage gap in which patients pay 47.5 percent of branded-drug costs and 79 percent of a generic's price. Russ Clifford, a retired music teacher, learned digoxin's cost had jumped more than fourfold when he picked up his 30-day supply in mid-November. Clifford and his wife have had to dip into savings to pay their rising pharmaceutical bills.[12]

[11] *See* http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-aslowdown-coming/.

[12] *See* http://www.bloomberg.com/bw/articles/2013-12-12/generic-drug-prices-spike-inpharmaceutical-market-surprise.

D. Government Investigation

62. Defendants' conduct in generic drug pricing is under investigation by the federal government, including the U.S. Senate and DOJ, as well as a state government investigation.

63. Taro Ltd.'s SEC Form 6-K, filed on September 9, 2016, announced that Taro Inc., "as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters."

64. Given the numerous approvals that must occur beforehand, when the DOJ issues grand jury subpoenas, there is a good likelihood that serious antitrust violations have occurred. The DOJ's *Antitrust Division Manual* provides that "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution."[13] And if a grand jury request memorandum is approved by the DOJ field office chief, "a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division]."[14] Then, "[t]he DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation."[15] Finally, "[t]he investigation

[13] *See Antitrust Division Manual*, Chapter III, Section F.1 at III-82 (2015).

[14] *Id.*

[15] *Id.* at III-83.

should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."[16]

65. The steep climb of generic drug prices of late is an issue of national importance. In addition to the DOJ subpoenas, Congress has taken a keen interest in the matter. For instance, in October 2014, Senator Bernie Sanders (I-VT) and Representative Elijah E. Cummings (D-MD) launched an investigation into the inexplicably soaring generic drug prices.

66. Sanders and Cummings issued a joint press release at the start of the investigation indicating that had issued letters to 14 pharmaceutical companies, advising "[w]e are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening illnesses." The bicameral duo noted the "huge upswings in generic drug prices that are hurting patients'" and having a "'very significant'" impact threatening pharmacists' ability to remain in business. The legislators made this issue a priority because, for some of their constituents, "the outrageous price hikes are preventing patients from getting the drugs they need.'"[17]

67. The U.S. Senate HELP Committee conducted a hearing on November 20, 2014, "Why Are Some Generic Drugs Skyrocketing in Price?"[18] The committee heard testimony from pharmacist, who explained "it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic

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[16] *Id.*

[17] Press Release, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

[18] http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.

drugs."[19] Using generic digoxin and doxycycline as examples of two of the generic drugs with price spikes, the pharmacist explained:

> A recent example from my own experience is the price of Digoxin- a drug used to treat heart failure. The price of this medication jumped from about $15 for 90 days' supply, to about $120 for 90 days' supply. That's an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).[20]

68. Additional congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate, Special Committee on Aging's December 9, 2015 hearing, the Director of the Drug Information Service of the University of Utah noted the deleterious effect these drug prices have had on patient access and healthcare: "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."

69. Following the DOJ opening its criminal investigation into Defendants' conduct on or about November 3, 2014, grand jury subpoenas have been issued to at least 14 generic drug companies, including all defendants.

[19] http://www.help.senate.gov/imo/media/doc/Frankil.pdf.

[20] *Id.*

70. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter requesting that the Office of the Inspector General ("OIG") of the Department of Health and Human Services "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs."[21] The OIG responded to the request on April 13, 2015 advising would examine pricing for the top 200 generic drugs to "determine the extent to which the quarterly [Average Manufacturer Pricing] exceeded the specified inflation factor."[22]

71. According to a November 3, 2016, *Bloomberg* report: "U.S. prosecutors are bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion" and that, according to the DOJ, "the first charges could emerge by the end of the year." As predicted, on December 12, 2016, the DOJ charged two generic industry executives with criminal counts related to price collusion for generic doxycycline hyclate and glyburide.

72. On December 15, 2016, several states' attorneys general, led by the State of Connecticut Office of Attorney General ("Connecticut AG"), filed a civil action for violation of the Sherman Act against Heritage Pharmaceuticals, Inc. and other sellers of generic doxycycline hyclate and glyburide, including defendant Mylan. The action filed by the attorneys general is styled *The State of Connecticut, et al. v. Aurobindo Pharma USA, Inc., Citron Pharms, LLC, Mylan Pharmaceuticals USA, Inc. and Teva Pharmaceuticals USA, Inc., Heritage Pharmaceuticals, Inc. and Mylan Pharmaceuticals, Inc.*, and is pending in U.S. District Court in Connecticut (16-cv-2056) (the "State AG Action").

[21] http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

[22] http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

73. According to the State AG Action, the information developed through its investigation (which is still ongoing) uncovered evidence of a broad, well-coordinated, and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the U.S. Although the State AG Action focuses of doxycycline hyclate and glyburide, it alleges that the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, including Defendant Mylan

74. The DOJ investigation of Defendants' alleged price-fixing conduct in the generic drug industry is ongoing.

VII. THE GENERIC DRUG MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

75. Because Defendants' anticompetitive conduct constitutes a conspiracy to fix prices, which is a *per se* violation of Section 1 of the Sherman Antitrust Act, Plaintiffs do not need to define a relevant market.

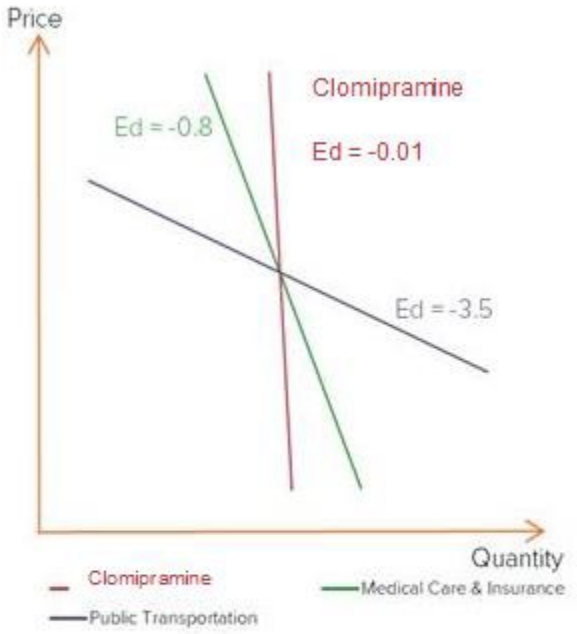
76. The factors necessary to show that a market is susceptible to collusion are present in this case:

(1) **High Level of Industry Concentration** – A small number of competitors (Defendants) control a significant market share for generic clomipramine, as detailed above. Indeed, Mylan and Taro together comprise about 95% of the market.

(2) **Sufficient Numbers to Drive Competition** – While the market for clomipramine had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near direct cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would remain at competitive levels.

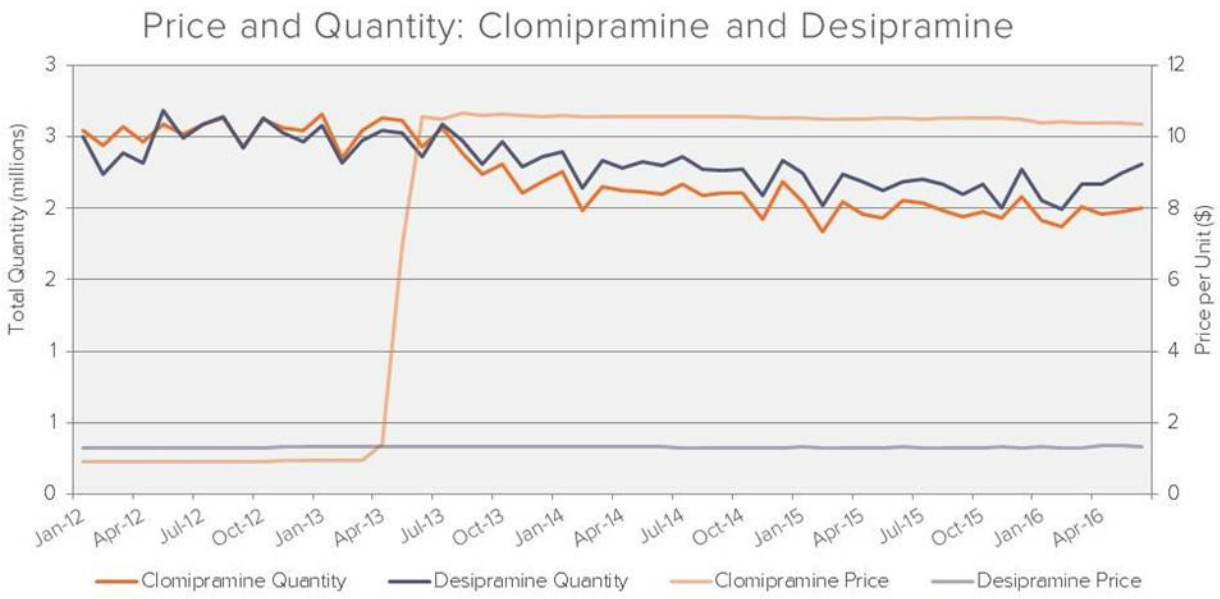
(3) **High Barriers to Entry** – The high costs of manufacture, intellectual property, and expenses related to regulatory approval and oversight are among the barriers to entry in the generic drug market. In addition, Defendants dominate the clomipramine market, one also considered too small on a worldwide basis to entice most of the world's major drug companies. By insulating against new entrants, these barriers to entry and others increase the market's susceptibility to a coordinated effort among the dominant players to maintain supracompetitive prices.

(4) **High Inelasticity of Demand** – For the hundreds of thousands of generic clomipramine prescriptions written annually, it is a necessity that must be purchased regardless of price hikes. This makes demand for clomipramine highly inelastic. In fact, clomipramine's demand curve is almost perfectly inelastic. As shown in the graph below, a 1037% increase in price for clomipramine leads to only a 12% decrease in quantity demanded. Compare this with medical care and insurance, though, where a 125% price increase would result in no more quantity being demanded. Defendants can exhibit cartel behavior due to this highly inelastic demand. Defendants can significantly raise clomipramine prices with minimal effect on quantity thus increasing overall revenue:

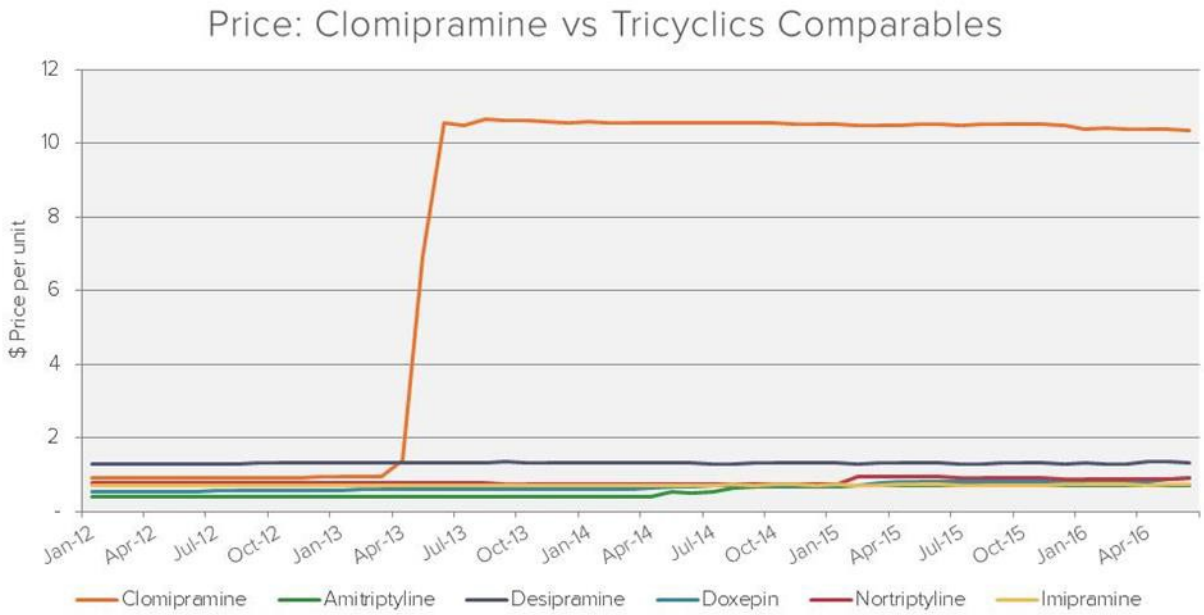


Examples	Ed	Price % Change	Qd % Change	Elasticity
Clomipramine	-0.01	1037%	-12%	Highly inelastic
Medical Care and Insurance	-0.80	125%	-100%	Relatively inelastic
Public Transportation	-3.50	29%	-100%	Highly elastic

(5) **Lack of Substitutes** – While there are other antidepressant drugs on the market, there are significant barriers to change treatments. Even with a large increase in price for clomipramine, very few users switched to another drug. For example, compare total sales for clomipramine to desipramine, another drug in the same class as clomipramine. The graph below shows sales for the two drugs between January 2012 and April 2016 and indicates that, despite the price hike, desipramine's sales remained steady. This lack of increase to desipramine's sales indicates that very few patients switched to another drug even in the face of a significant price spike:



Moreover, the price increases on clomipramine did not extend to the other drugs in its class. From January 2012 through April 2016, for instance, the prices of amitriptyline, desipramine, doxepin, nortriptyline and imipramine, all drugs that have similar clinical effect to clomipramine, remained at consistent prices despite defendants' jaw-dropping clomipramine price hikes:



(6) **Commoditized Market** – Defendants' generic clomipramine products are fully interchangeable, because they are bioequivalent to one another by FDA standards.

Thus, all manufactured versions of clomipramine are therapeutically equivalent to each other and pharmacists may substitute one for another interchangeably.

(7) **Absence of Departures from the Market** – There were no departures form the market that could explain the price increases.

(8) **Absence of Non-Conspiring Competitors** – Defendants have maintained supracompetitive pricing for generic clomipramine throughout the Class Period. Thus, defendants have oligopolistic market power in the generic clomipramine market, which enabling price increases without loss of market share to non-conspirators. Indeed, no competitors not part of the conspiracy have emerged to undercut the defendants' supracompetitive pricing.

(9) **Opportunities for Contact and Communication Among Competitors** – Defendants participate in the committees and events of the GPhA, which provides and promotes opportunities to communicate. The grand jury subpoenas to defendants targeting inter-defendant communications, further supports the existence of communication lines between competitors with respect to, among other things, generic clomipramine pricing.

(10) **Size of Price Increases** – The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Oligopolists seeking to test market increases need to take measure approaches. But here the increases are not 5% or even 10% jumps – the increases are, in just one act, more than eight times the current price of the product. A rational oligopolist, when unaided with the certainty that its ostensible competitors would follow, would not do so.

(11) **Reimbursement of Generic Drugs** – This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, the usual inhibition of an oligopolist to unilaterally raise prices are embedded in the generic reimbursement system. In the absence of coordinated pricing activity

> among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales. However, when one observe significant price increases – particularly those of the kind alleged here – basic market economics dictates that the generic drug makers likely ad an expectation that they would not lose volume (based on their expectations of what their ostensible competitors would do) – because they colluded.

77. Though it is not necessary to allege a relevant market, at all relevant times, Defendants had substantial market power (*i.e.*, monopoly power) with respect to generic clomipramine because they had the power to maintain the price of the drug at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

78. A small but significant, non-transitory price increase above the competitive level for clomipramine by Defendants would not have caused a loss of sales sufficient to make the price increase unprofitable.

79. Generic clomipramine does not exhibit significant, cross-price elasticity of demand with respect to price with any product other than other AB-rated generic versions of clomipramine.

80. The existence of other medications for the treatment of severe inflammatory skin infections did not constrain Defendants' ability to raise or maintain the price of clomipramine without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market with clomipramine. Therapeutic alternatives are not the same as economic alternatives.

81. Because of its labeling, clomipramine is differentiated from all products other than brand and AB-rated generic versions of clomipramine.

82. Defendants sold clomipramine at prices well in excess of marginal costs, and in excess of competitive price, and enjoyed high profit margins.

83. Defendants have had, and exercised, the power to exclude and restrict competition to clomipramine.

84. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to regulatory protections and high costs of entry and expansion.

85. To the extent that Plaintiffs are legally required to prove substantial market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is generic clomipramine or narrower markets contained therein. During the relevant time, Defendants were able to profitably maintain the price of clomipramine substantially above competitive levels.

86. The relevant geographic market is the United States and its territories.

87. At all relevant times, Defendants' market share of the relevant market exceeded 97%, implying a substantial amount of market power.

88. Through their market dominance, Defendants' have been able to substantially foreclose the market to rival competition, thereby maintaining and enhancing market power and enabling Defendants to charge Plaintiffs and the proposed Class Members inflated prices above competitive levels for generic clomipramine through unlawful price collusion.

VIII. CLASS ACTION ALLEGATIONS

89. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiffs bring this action on behalf of a Class defined as:

> All persons or entities that directly purchased generic clomipramine from one or more of Defendants in the United States

> and its territories and possessions at any time during the period from May 3, 2013 through the present (the "Class Period").
>
> Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities

90. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that there are dozens of Class Members, geographically dispersed throughout the United States such that joinder of all Class Members is impracticable. Further, the Class is readily identifiable from information and records maintained by Defendants.

91. Plaintiffs' claims are typical of, and not antagonistic to, the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.

92. Plaintiffs will fairly and adequately protect and represent the interests of the Class and Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

93. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

94. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class. Thus, determining damages with respect to the Class as a whole is appropriate. The common applicability of the relevant facts to claims of Plaintiffs and the proposed class is inherent in Defendants' wrongful conduct, because the overcharge injuries incurred by Plaintiffs and each member of the proposed class arose from the same collusive conduct alleged herein.

95. The common legal and factual questions do not vary among class members and may be determined without reference to individual circumstances, and include, but are not limited to, the following:

(a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby increase the prices of generic clomipramine in the United States;

(b) The duration and extent of the alleged contract, combination, or conspiracy between and among Defendants and their co-conspirators;

(c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;

(d) The effect of the contract, combination, or conspiracy on the prices of generic clomipramine in the United States during the Class Period;

(e) Whether Defendants' conduct caused supracompetitive prices for generic clomipramine;

(f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiffs and other members of the Class; and

(g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

96. Treatment as a class action is the superior method for the fair and efficient adjudication of this controversy, as it will permit numerous similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, avoiding unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

97. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. ANTITRUST INJURY

98. During the Class Period, Plaintiffs and Class Members directly purchased generic clomipramine from Defendants. Because of the Defendants' anticompetitive conduct, Plaintiffs and Class Members were forced to pay more for generic clomipramine than they otherwise would have, and thus have suffered substantial overcharge damages at the hands of Defendants. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

99. Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiffs and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such overcharge damages will be calculated after discovery and upon proof at trial.

100. Defendants', through their unlawful conduct alleged herein, reduced competition in the generic clomipramine market, increased prices, reduced choice for purchasers, and caused antitrust injury to purchasers in the form of overcharges.

101. Because Defendants' anticompetitive conduct is ongoing, Plaintiffs and the Class continue to pay supracompetitive prices for generic clomipramine through the present.

X. CLAIM FOR RELIEF – VIOLATION OF SECTION 1 OF THE SHERMAN ACT

102. Plaintiffs repeat and re-allege the foregoing as though fully set forth herein.

103. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

104. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

105. In violation of Section 1 of the Sherman Antitrust Act, Defendants entered agreements with one another concerning the pricing of generic clomipramine in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

106. Each of the Defendants has committed at least one overt act to further the conspiracy alleged in this Complaint.

107. The conspiracy had its intended effect, because Defendants have benefited—and continue to benefit—from their collusion and the elimination of competition, both of which artificially inflated the prices of generic clomipramine.

108. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and Class Members have been injured in their business and property in that they have paid more for generic clomipramine than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial, but is believed to be in the hundreds of millions of dollars classwide.

109. Defendants' unlawful conduct as alleged herein poses a significant and continuing threat of antitrust injury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Class Members pray for relief from this Court and request:

A. Certification as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiffs as Class Representative and their counsel of record as Class Counsel;

B. Adjudication that the acts alleged herein constitute unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

C. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiffs and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

D. An award to Plaintiffs and Class Members of pre-judgment and post-judgment interest at the highest legal rate provided by law from and after the date of service of this Complaint;

E. An award to Plaintiffs and Class Members of the costs of this suit, including reasonable attorney fees; and

F. An award of any further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby request a jury trial on all claims so triable.

Dated: January 30, 2017

Respectfully submitted,

/s/ John D. Radice

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